

PMUSA Clinical Evaluation Study Plan Worksheet

PMUSA CE Study Tracking Number: _____ (MUST be used on ALL study communications)

Study Manager (SM): _____ **Tel:** _____

Study Statistician (SS): _____ **Tel:** _____

CRO _____ **CRO Study Tracking Number:** _____

Project Manager: _____ **Tel:** _____

Study Manager: _____ **Tel:** _____

Key Site Personnel:

Pharmacist: _____ **Tel:** _____

Topography: _____ **Tel:** _____

WatchPC: _____ **Tel:** _____

Monitoring CRO _____

Program Manager: _____ **Tel:** _____

Min. Time Required for Task	Projected Study-Specific Date	Task or Milestone (initiated by SM unless noted otherwise)
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Clinical Study Team[†] designs study.

Study Manager presents proposed study design for review to CE.

Operations constructs study timeline & inserts in overall project timeline

SM or CPL presents proposed study for review to

WSA [RDE Staff (RS) or R&C (GP)] and/or DRB (JN):

- ☐ Purpose and Objectives (scientific AND business)
- ☐ Relevant background support data
- ☐ Design (endpoints, time-event schedule, data analysis)
- ☐ Study timeline; how fits into overall project timeline
- ☐ Limitations (of design, schedule, results)

(days to IRB review)

7 workdays

(~10 calendar days)

Protocol outline to Scientific Writer

Initiate contract process.

Notify Legal of anticipated review date.

Notify appropriate key partners:

- ☐ conventional cigarette(s) needed [qty (MC), smoke chem (PTL)]
- ☐ investigational cigarette(s) needed [qty, smoke chem (PTL)]
- ☐ Product Coordinator re Investigator's Brochure
- ☐ topography
- ☐ WatchPC
- ☐ monitoring CRO re monitoring plan
- ☐ bioanalytical assays
- ☐ ETS
- ☐ Discuss recruitment plan w/ CRO (Project Manager and Recruitment Manager)

6 workdays (~9 calendar days)	Draft protocol, attachments, ICF to Study Manager, then Clin Study Team, for review. Study Manager collates comments.
3 workdays (~3 calendar days)	Scientific Writer incorporates PMUSA comments.
8 workdays (~10 calendar days)	Draft final protocol, attachments, ICF to Dir Clin Ops, then Legal, for review. Study Manager collates final comments.
2 workdays (~2 calendar days)	Scientific Writer incorporates final PMUSA comments.
1 workday (Wed.) (~2 calendar days)	Final protocol, attachments, ICF to IRB Secretary and Study Manager
5 workdays (Tues.) (~7 calendar days)	IRB review
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<u>(in calendar weeks hereafter)</u>	
9 weeks	Subject recruitment begins. Study Manager notifies PMUSA Consumer Response Center. Study Manager reviews CRF and ClinQuick™ clinical conduct plan.
at ~4 weeks prior to start of clinical conduct	Site initiation visit (required for any sites NEW to PMUSA)
at ~2 to 4 weeks prior to start of clinical conduct	Study initiation visit
varies (study-determined)	Clinical conduct: First subject, first visit (FSFV) Clinical conduct: Last subject, last visit (LSLV)
2 weeks from LSLV	Clinical Database Lock (CDBL) Monitoring begins.
N.B.: When available, preliminary* subject listings by analytical batch for 24h or fractional urine volume and creatinine (concentration and amount excreted) will be provided to Study Manager for procedural compliance evaluation.	
3-5 months from LSLV	Analytical Database Lock (ADBL) N.B.: <i>Progressive, staged</i> ADBL may occur, with routine biomarkers locked at approx. 3 months after LSLV and any problematic biomarkers locked by 5 months after LSLV.
1 week from ADBL	Statistical Database Lock (SDBL) IF: <ul style="list-style-type: none"> ○ SAP accepted. ○ Monitoring completed. N.B.: <i>Progressive, staged</i> SDBL may occur, if <i>progressive, staged</i> ADBL occurred.
2 weeks from SDBL (staged or full)	All Tables and Figures for locked biomarkers provided to: <ul style="list-style-type: none"> ○ Study Manager for internal CE review. ○ Scientific Writer to begin writing draft CSR.

8 weeks from SDBL	Draft CSR to Study Manager.
5 weeks	Clin Study Team reviews Draft CSR. Study Manager sends PMUSA comments to Scientific Writer.
4 weeks	Scientific Writer revises Draft CSR and sends Final CSR to Study Manager.
1 week	Clin Study Team reviews Final CSR.

LEGEND

* *Clin Study Team* = *Clinical Program Leader (CPL)* +
Study Mgr (SM) +
Study Statistician (SS)
 with input from *Marketing*, *Bioanalytics (BA)*, *Smoking Behavior (SB)*, and *Director Clin Ops*

ADBL analytical database lock
CE Clinical Evaluation
CDBL clinical database lock
COHb carboxyhemoglobin
CRA Clinical Research Associate
CRF case report form
CRO Clinical Research Organization
CSR clinical study report
DRB Design Review Board
ETS environmental tobacco smoke
ICF informed consent form
IRB Investigational Review Board
MC Manufacturing Center
PMUSA Philip Morris USA, Inc.
PTL Product Testing Lab
QC quality control
R&C Research Results and Concepts meeting
RDE Research, Development & Engineering
SAP statistical analysis plan
SDBL statistical database lock

* preliminary data = non QCd data released before statistical database lock
 On occasion, PMUSA may request release of preliminary data for a specific biomarker in the form of data listings and summary statistics to evaluate key clinical procedural compliance or to help make critical business or product development decisions.